TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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DAVID L. LAKEY, M.D.
COMMISSIONER

April 16, 2010

The Honorable Edward J. Markey, Chairman
Subcommittee on Energy and Environment
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6155

Dear Chairman Markey:

Thank you for your letter dated March 18, 2010 requesting information regarding Texas' regulation of medical patients being treated and released with medical isotopes. Radiation Control rules are posted on our website at http://www.dshs.state.tx.us/radiation/rules.shtm. The US Nuclear Regulatory Commission (NRC) has determined that the programs administered by the Department of State Health Services (DSHS) are compatible with federal requirements and adequate to protect public health and safety in Texas.

Texas is an Agreement State. The DSHS Division for Regulatory Services regulates the safe use of radioactive materials in Texas and oversees the regulation of radioactive materials licensees, users of x-ray and laser devices, and performs emergency planning and response to radiological accidents.

I have enclosed responses to your questions. If you need additional information or further clarification, please do not hesitate to contact me.

Sincerely,

Richard A. Ratliff, P.E., L.M.P.,
Radiation Safety Licensing Branch Manager
Division for Regulatory Services
Texas Department of State Health Services
Mail Code 2835
PO Box 149347
Austin, Texas 78714-9347

Enclosure

Chairman Markey Response

Question 1:
How many iodine-131 (1-131) licensee facilities are overseen by your State?

Response 1:
We have 231 licensees that are authorized to use Iodine 131 in therapeutic quantities (i.e., quantities that exceed 30 microcuries, which require a written directive).

Question 2:
How often does your State perform sampling inspections at each of these 1-131 licensee facilities?

Response 2:
Radioactive materials (RAM) licenses authorizing Iodine-131 therapy are inspected on a two year interval. Each inspection is a complete review of the licensee's performance in compliance with the rules and license conditions pertaining to the authorized use of RAM.

Question 3:
What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Response 3:
Every RAM inspection includes observations and interviews in addition to document and record reviews. RAM inspectors use inspection forms to assist them in performing a complete inspection. While part of the form may be used as a check list, the inspector is required to submit information in a narrative format that describes the information in greater detail. Items that are not in compliance with the regulations or license conditions are completely described and documented in the report. These reports are then used in the enforcement process. The forms are specific to the type of activities authorized to be performed by the RAM license. Attached to this response is a copy of the inspection form used for license inspections of facilities performing medical therapy using RAM. All forms note the specific rule citations for the activities being inspected. The information most pertinent to your questions may be found in the section covering "sealed and unsealed therapy program information." This is on page 8 and 9 of the form.
Every section of the report is important in ascertaining the complete status of a facility's program.

Question 4:
NCRP 155, includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients"[4]. For a patient receiving 175 millicuries of 1-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

Response 4:
Texas' dose limits and restrictions are required to be compatible with the NRC's. We have

adopted the same requirement as NRC and are not more restrictive. These rules found in 25TAC289.256(cc) set out the requirements that our licensees must follow.

Question 5:
In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with 1-131 in excess of the default limits home, or to a hotel?

Response 5:
Every RAM inspection includes a review of records the licensee is required to maintain by rule or license condition. Any records required to be maintained regarding patient release would be included.

Question 6:
In the past ten years, how many times has your state, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?

Response 6:
As noted above all inspections would include interviews, observations and a review of documentation and records of the items covered by the rules and license conditions for the particular RAM use authorization.

Question 7:
In the past ten years, how many times has your state identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

Response 7:
Departmental data is not tracked in the manner requested in your letter. A complete inspection report is submitted for every inspection and each inspection report is subjected to a quality assurance review. Notices of violation are sent to licensees who are in non-compliance with any rules or license conditions. An enforcement process exists which allows for administrative penalties to be charged for items of non-compliance. While the actual data can not be tracked, an informal survey of report reviewers indicated that non-compliance with the rules regarding patient release and dose to the public is rare.

Question 8:
In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

Response 8:
Texas believes that a licensee is quite capable of calculating conservative dose estimates using reasonable assumptions concerning occupancy, building geometry, and other factors. In all outpatient cases, one cannot possibly control what the patient does when they leave the licensed facility.

Question 9:
Has your State ever attempted to determine how many patients treated with 1-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?

Response 9:
No. Texas does not track the destinations of released patients from medical institutions. Instead, during onsite inspections at medical facilities, inspectors review a representative sample of cases involving therapeutic uses of radioactive materials to determine from patient records the circumstances whereupon the patient was released and the content of the counseling the patient received. These reviews are used to verify compliance with the regulations regardless of the patient's final destination.

Question 10:
In patients with doses in excess of the default limits, has your State ever attempted to determine whether these 1-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has NRC ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.

Response 10:
As discussed in responses above, Texas inspectors evaluate the licensee's program for patient release to verify compliance with Texas' requirements. We have not found any situations where the dose calculations were not performed.

Question 11:
What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?

Response 11:
Texas does not have any such disclosure rules for patients to give to hotels. Instead we recommend that our licensees refer to the NRC's guidance for medical use licensees which contains general objectives rather than prescriptive directions. Texas requires the instructions to include actions the licensee recommends that meet the general objective of maintaining doses to other individuals as low as reasonably achievable, but licensees are not required to give patients explicit instructions to provide to hotel management. Guidance in NUREG-1556, Volume 9, Revision 2, Appendix U describes in general terms how licensees can meet this performance-based objective. This document gets reviewed and updated periodically by the NRC and we make the necessary changes at that time if any are necessary.

Question 12:
Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels: If so, please provide copies.

Response 12:
No.

Question 13: Are your licensees required to report to you any instances in which released I-131 patients caused radiation exposure to family members or members of the public?

Response 13:
Texas does not require such a report. Once a patient is released there are no further requirements for either the patient or the licensee.

Question 14: Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radionuclides.

Response 14:
The only correspondence we have is the routine review of our program through the Integrated Materials Performance Evaluation Program (IMPEP). These reports can be found on the NRC's website as follows: http://nrc-stp.ornl.gov/rulemaking.html#Tx

Question 15:
Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

Response 15:
Departmental data is not tracked in the manner requested in your letter. A complete inspection report is submitted for every inspection and each inspection report is subjected to a quality assurance review. Notices of violation are sent to licensees who are in non-compliance with any rules or license conditions. An enforcement process exists which allows for administrative penalties to be charged for items of non-compliance. While the actual data can not be tracked, an informal survey of report reviewers indicated that non-compliance with the rules regarding patient release and dose to the public is rare.

Texas Department of State Health Services
Inspection Unit

Inspection date: Type:	**Radioactive Materials** **Medical Therapy Inspection**	License No.: **L** - Compliance number: **R**

License Name: Address:	Expiration date:	Permit status: Inspection region:
	RSO:	
	RSO phone: Company phone:	Site phone: Site fax:
	Use:	

Inspection address or location:	Inspection notice to:	Copy of notice to:

☐ Requested electronic copy of NOV be emailed to:

Exit interview with:

Inspector:	Report date:	PRN: 4/16/2010 8:16:00 AM
Other inspectors: **None**	Reviewed by:	Date reviewed:
Additional pages: **0** / IC inspection performed:		

Inspection findings:

Licensee:	**Medical Therapy Inspection**	Inspection Date: License No.: **L** -
Program and Management Information		
1. Scope of Operations		
2. Inspector Notes	Note any special protective equipment needed, unusual site location, and non-standard contact info.	
3. Increased Controls 252(ii) & (jj)(9)	☐ Yes ☐ No Single source or co-location of RAM in Quantities of Concern was possessed during the inspection period of review? Violation/Comment:	
4. Inspection History and Incidents	If this is the initial inspection, enter the date of first receipt of licensable RAM: Last routine inspection date: Number of Violations: **0** ☐ Yes ☐ No ☐ N/A Were all violations corrected (list uncorrected below)? ☐ Yes ☐ No Reportable incidents since last inspection? --If **Yes**, reported to agency properly? ☐ Yes ☐ No Violation/Comment:	
5. Radiation Safety Committee 256(i) or License Condition ☐ **N/A**	☐ Yes ☐ No Meetings performed at the minimum required interval. ☐ Yes ☐ No Appropriate representation on the radiation safety committee. ☐ Yes ☐ No Records of meeting minutes available. ☐ Yes ☐ No Reviewed records complete and cover appropriate topics. Violation/Comment:	
6. Management Information	Authorized Radiation Safety Officer: ☐ Yes ☐ No Currently acting as RSO? -- If **No**, list designee: -- **If** site RSO's are authorized, list authorized site RSO: -- ☐ Yes ☐ No Currently acting as site RSO? -- If **No**, list designee: Persons present for inspection: Violation/Comment:	
7. Radiation Safety	☐ Yes ☐ No RSO reviews of radiation safety program performed at appropriate interval? ☐ Yes ☐ No RSO review performed by authorized individual? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:	
8. Posting of Documents and Availability	☐ Yes ☐ No Texas Rules available on-site? 203(b)(1)(A) Form of rules: Records location: ☐ Yes ☐ No License available? 203(b)(1)(B) Amendment. # **00** Dated: ☐ Yes ☐ No Operating Procedures available? 203(b)(1)(C) ☐ Yes ☐ No ☐ N/A Notice of Violation and/or agency orders available? 203(b)(1)(D) ☐ Yes ☐ No Documents and Notice to Employees posted properly? 203(b)(3) Violation/Comment:	
9. Radiation Protection Program 202(e)(1) or (3), (mm)(1)(A) or (B)	☐ Yes ☐ No Plan developed, documented and implemented? ☐ Yes ☐ No ☐ N/A Annual reviews documented? Review Dates: Violation/Comment:	
10. Worker Training & Personnel Qualifications and Supervision	☐ Yes ☐ No 203(c) Instructions to workers for persons likely to exceed 100 mrem/yr. ☐ Yes ☐ No Technicians are appropriately certified to perform procedures/treatments. ☐ Yes ☐ No Records of technician certifications were available. ☐ Yes ☐ No Technicians are supervised by authorized users. ☐ Yes ☐ No All physicians are authorized on the license. Violation/Comment:	
11. Public Dose Assessment 202(n) and (o)	How was annual dose determined? 202(n)(1)(A) ☐ Yes ☐ No Unrestricted area surveys performed? (202(n)(1)(B) Hourly exposure rate) ☐ Yes ☐ No Surveys documented? (202(n)(1)(B) Hourly exposure rate) ☐ Yes ☐ No Licensee records adequate to show public dose limits were not exceeded? Violation/Comment:	
12. Performance Based		
Comments/Violation:		

Medical Therapy Inspection Inspection Date:

Licensee: License No.: L -

Radioactive Material Management

1. Physical Inventory 256(z)(2) 252(f)(3)(L) ☐ N/A	Required to perform a physical inventory of sealed sources at 6 month interval. ☐ Yes ☐ No Performed at required interval? ☐ Yes ☐ No Periodic inventories documented and radionuclide activity within authorization? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:
2. Inspection and Maintenance ☐ N/A	Required by **rule**: # Required interval: ☐ Yes ☐ No Performed at the required interval? ☐ Yes ☐ No Performed by authorized individual? ☐ Yes ☐ No Periodic inspections and maintenance documented? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:
3. Receipt **Transfer** **Disposal** [decay in storage 256(ee)] **Records**	Radioactive material received since last inspection? ☐ Yes ☐ No Radionuclides received were authorized by license? ☐ Yes ☐ No Total possession limits were not exceeded? Radioactive material transferred since last inspection? ☐ Yes ☐ No Radioactive material transferred to authorized recipient? Radioactive material disposed since last inspection? ☐ Yes ☐ No Disposal performed using authorized method & disposed properly? 202(ff)-(kk) List methods of disposal used: Methods of disposal authorized by : ☐ Yes ☐ No Records available? ☐ Yes ☐ No Reviewed records include all required information? 201(d)(1) Violation/Comment:
4. National Source Tracking System (NSTS) **202(hhh)** ☐ N/A	When sources requiring NSTS tracking were possessed during the inspection period of review: ☐ Yes ☐ No ☐ N/A Initial inventory appropriately reported & documented in the NSTS by Jan. 31, 2009? (for those possessing NSTS sources prior to 2/1/09) ☐ Yes ☐ No Transactions (receipt, transfer, disposal, destruction, & manufacture) reported & documented appropriately? (including corrections and missed transactions) ☐ Yes ☐ No ☐ N/A Annual reconciliations were reported & documented appropriately? Violation/Comment:
5. Installation and Survey ☐ N/A	Required by license condition: # ☐ Yes ☐ No Installer authorized? -- If No, List name: ☐ Yes ☐ No Survey performed? ☐ Yes ☐ No Survey recorded? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:
6. Utilization Records ☐ N/A	Required by **rule:** ☐ Yes ☐ No Radioactive material use documented when required? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:
7. Leak Tests 201(g)(1) ☐ N/A **201(g)(2)(F) 201(g)(1)(A)**	Method of sample collection: ☐ Yes ☐ No Tests performed at the required **6 month** interval? ☐ Yes ☐ No Analysis performed by authorized person? ☐ Yes ☐ No Leakage found? -- If **Yes**, reported to agency appropriately? ☐ Yes ☐ No ☐ Yes ☐ No ☐ N/A Leak tests were performed within 6 months prior to use for sealed sources removed from storage, or received from another licensee? ☐ Yes ☐ No ☐ N/A If licensee performs leak test analysis, are procedures being followed? ☐ Yes ☐ No Reviewed test records include all required information? Violation/Comment:
8. Performance Based	
Comments/Violation:	

Medical Therapy Inspection Inspection Date:

Licensee: License No.: L -

Radiation Surveys and Instrumentation

1. Use Area Surveys 202(p)(1) ☐ N/A	☐ Yes ☐ No Surveys performed? ☐ Yes ☐ No Surveys documented? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:
2. Storage Area Surveys 202(p)(1) ☐ N/A	☐ Yes ☐ No Surveys performed? ☐ Yes ☐ No Surveys documented? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:
3. Area Wipe Surveys and Other Surveys 202(p)(1) ☐ N/A	☐ Yes ☐ No Surveys performed? ☐ Yes ☐ No Surveys documented? ☐ Yes ☐ No Reviewed records include all required information? Violation/Comment:
4. Package Receipt Procedures and Surveys ☐ N/A	☐ Yes ☐ No Package receipt procedures available and complete? ☐ Yes ☐ No ☐ N/A Contamination surveys of package surfaces were performed for Labeled, Normal form RAM. ☐ Yes ☐ No ☐ N/A Radiation level surveys of external surfaces were performed for Labeled, greater than Type A RAM. ☐ Yes ☐ No ☐ N/A Contamination and radiation level surveys were performed when there was evidence of degradation of package integrity. ☐ Yes ☐ No Surveys were performed within 3 hours of receipt, or within 3 hours after beginning the next working day. ☐ Yes ☐ No Removable contamination limits and external radiation limits were not exceeded? Violation/Comment:
5. Instrument Calibration 202(p)(2) ☐ N/A	Required calibration frequency: ☐ Yes ☐ No Calibrations performed by authorized persons, after repair, appropriate radiation type and energy, and accuracy within 20%? ☐ Yes ☐ No Instruments used for quantitative radiation measurements only when calibrated within required interval? ☐ Yes ☐ No --**If** licensee performs calibrations, are procedures followed? Violation/Comment: List instruments used for quantitative radiation measurements for which survey records were reviewed. (eg.: portable, analytical, area monitors, air samplers/sampler calibrators, etc…)

Make	Model	Serial Number	Range	Calibration Date(s)
	Violation/Comment:			

6. Performance Based	
Comments/Violation:	

Licensee:	**Medical Therapy Inspection**	Inspection Date: License No.: L -
Inspector Facility and Equipment Inspection		
1. Facilities	☐ Yes ☐ No Are facilities (buildings, labs, storage, and use areas, etc.) unchanged from the facilities depicted in drawings and information submitted with the application? -- If **No**, describe differences in comments. Violation/Comment:	
2. Posting 202(aa)(1) ☐ **N/A**	☐ Yes ☐ No Are use and storage areas posted as required? -- If **No**, describe deficiency in comments. Violation/Comment:	
3. Container Labeling ☐ **N/A**	Description of device(s): Labeling: ☐ Yes ☐ No Legible labels affixed. Labels show: ☐ Yes ☐ No "Caution - Radioactive Material" and radiation symbol. ☐ Yes ☐ No Contents description ☐ Yes ☐ No Other Violation/Comment:	
4. Container Security	Describe security of radioactive material: Violation/Comment:	
5. Performance Based		
Comments/Violation:		

Licensee:	**Medical Therapy Inspection**	Inspection Date: License No.: L -
	Occupationally Exposed Personnel	
1. Dosimetry Program	☐ Yes ☐ No Does the licensee provide appropriate personnel monitoring for occupationally exposed individuals? ☐ Yes ☐ No Has the licensee determined that personnel are not likely to receive a dose in excess of 10% of the appropriate limits? Documentation required by 202(e)(5) ☐ Yes ☐ No Have operations been performed under the Planned Special Exposure rule? Violation/Comment:	
2. Dosimetry Supplier	Dosimetry Supplier: Radiation types at this site: ☐ Yes ☐ No Dosimetry supplier is accredited by NVLAP for the radiation types monitored. Violation/Comment:	
3. Dosimetry Provided (Adult)	Monitoring Method / Exchange Frequency / Dosimeter Type / Location Worn **Whole Body** **Extremity** ☐ Yes ☐ No Dosimetry worn appropriately and handled properly? 202(r) ☐ Yes ☐ No Control badges maintained appropriately? Violation/Comment:	
4. Bioassays ☐ N/A	☐ Yes ☐ No Bioassay procedures followed? ☐ Yes ☐ No Reviewed bioassay records available and complete? ☐ Yes ☐ No Bioassay results within regulatory limits? Violation/Comment:	
5. External & Internal Dose (Adult) **202(j)**	Monitoring Year:---------- **Current** Maximum TEDE mRem: --- -DDE portion mRem--------- -CEDE portion mRem ------- Maximum Extremity mRem- ☐ Yes ☐ No ☐ N/A Was the dose from previous employers included in TEDE? Violation/Comment:	-If TEDE includes internal dose, describe internal dose monitoring program.
6. Dose Records	☐ Yes ☐ No Documents used in preparing 202-3's maintained for 3 years? ☐ Yes ☐ No 202-3's, or equivalent, available for previous years? ☐ Yes ☐ No 202-3's, or equivalent, completed by April 30th for previous years? Violation/Comment:	
7. Declared Pregnancy ☐ N/A	☐ Yes ☐ No Was the pregnancy declared in writing to the licensee? ☐ Yes ☐ No Was dosimetry provided and the dose managed as required by §289.202(m)? Violation/Comment:	
8. Monitoring of Minors ☐ N/A	☐ Yes ☐ No Were minors monitored appropriately? (Annual limits are 10% of adult limits) Maximum whole body TEDE for minors: Violation/Comment:	
9. Pocket Dosimeters ☐ N/A	☐ Yes ☐ No Appropriate range used? Range used: ☐ Yes ☐ No Calibrated by authorized person and at appropriate interval? Violation/Comment:	
10. Alarming Rate Meters ☐ N/A	Alarm set point maintained at: ☐ Yes ☐ No Calibrated by authorized person and at appropriate interval? Violation/Comment:	
11. Overexposures	☐ Yes ☐ No Have any overexposures occurred since the previous inspection? -- If **Yes**, Was notification to the agency within the required period? ☐ Yes ☐ No -- **and** Was there proper notification to the overexposed individual? ☐ Yes ☐ No Violation/Comment:	
12. Notifications of Dose 203(d)	☐ Yes ☐ No Annual dose provided in writing upon written request by employee? ☐ Yes ☐ No ☐ N/A The licensee provides written reports of individual's exposures to radiation at the request a worker no longer employed by the licensee? Violation/Comment:	
13. Performance Based		
Comments/Violation:		

Licensee:	**Medical Therapy Inspection**	Inspection Date: License No.: L -
	Radioactive Materials Transportation	
1. RAM Offered for Transport	☐ Yes ☐ No Has the licensee transported or offered for transport radioactive material during the period of review of this inspection? Violation/Comment:	
2. Hazmat Training ☐ **N/A** **257(e)(1)(F)** **49 CFR 172.702** **49 CFR 172.704**	☐ Yes ☐ No Hazmat employees have received initial general awareness, function specific, safety, and security awareness training within 90 days of employment or change in job function? ☐ Yes ☐ No Hazmat employees have received recurring training within 3 year interval? ☐ Yes ☐ No A record of training for the previous 3 years is maintained? ☐ Yes ☐ No Reviewed training records include all required information? 49 CFR 172.704(d) Violation/Comment:	
3. Packages **257(l)(9)** **257(l)(10)**	Types of packages used: ☐ Yes ☐ No Appropriate certification documents maintained for the packages used? 257(i) ☐ Yes ☐ No ☐ N/A For Type B packages, the licensee has an approved quality assurance program, and registered with the NRC for use of the package? 257(i) ☐ Yes ☐ No Labeling of packages appropriate? 257(e)(1)(B) ☐ Yes ☐ No Marking of packages appropriate? 257(e)(1)(B) ☐ Yes ☐ No Packages surveyed - removable contamination within limits of 49 CFR 173.443, and external radiation within limits of 257(l)(10). Note any package survey results in excess of applicable limits. Violation/Comment:	
4. Records of Shipments and Shipping Papers	☐ Yes ☐ No Shipping papers maintained for 2 years. (3 years for hazardous waste) - 49 CFR §172.201(e) ☐ Yes ☐ No Reviewed shipping papers were complete? 257(e)(1)(E) & 49 CFR 172.200 ☐ Yes ☐ No Emergency response information available? 257(e)(1)(E) & 49 CFR 172.600 ☐ Yes ☐ No Were records of shipments maintained for the 3 years? -257(o) ☐ Yes ☐ No Reviewed records of shipments contained all required information? - 257(o) Violation/Comment:	
5. Transport Vehicles ☐ **N/A** **257(e)(1)**	Vehicles used for transport: ☐ Yes ☐ No ☐ Undetermined Carrier vehicles comply with appropriate requirements? (driver hazmat training, shipping paper accessibility, exclusive use instructions, packages secure in vehicle.) ☐ Yes ☐ No ☐ Undetermined Vehicle surveys performed by licensee? Violation/Comment:	
6. Inspector Survey ☐ **Not Performed**	**Packages:** Violation/Comment: **Vehicles:** Violation/Comment:	
7. Performance Based		
Comments/Violation:		

Medical Therapy Inspection Inspection Date:

Licensee: License No.: L -

Sealed & Unsealed Therapy Program Information

1. Radioactive Material Authorized by License

Material possession/used/storage during period of review:
(N = not possessed, U = used, S = only in storage) * = special form
Sealed: I-125 Pd-103 Cs-137* Ir-192 wire/seeds Ir-192* HDR
Sr-90 Others
Unsealed: ☐I-131 cap ☐I-131 liquid ☐I-131 i.v. ☐Sr-89 ☐Sm-153 ☐Y-90 ☐P-32 ☐Others
Approximate numbers of procedures per month (total):
Significant program changes:
Violation/Comment:

2. Dose Determination

☐ Yes ☐ No Determination of dose made prior to medical use? 256(x)
--Methods used: ☐Dose calibrator direct measurement ☐Decay correction ☐±15 minutes UD
☐ Yes ☐ No Dose determination record includes appropriate information? 256(x)(5)
Violation/Comment:

3. Dose Calibrators

☐ N/A

Linearity 256(v)(3)(B)
Accuracy 256(v)(3)(D)

☐ Yes ☐ No Daily constancy testing performed? 256(v)(3)(A)
☐ Yes ☐ No Geometry dependence test performed at installation? 256(v)(3)(C)

Mfg. & Model	S/N	Performed By	Linearity Test Dates (quarterly)	Accuracy Test Dates (annual)

Violation/Comment:

4. Written Directives and Procedures 256(t)

☐ N/A

☐ Yes ☐ No Written procedures for administrations requiring written directives were developed, implemented, and maintained? 256(t)(4)
☐ Yes ☐ No Reviewed written directives contain the appropriate information? 256(t)(2)
☐ Yes ☐ No Written directives maintained for 3 years? 256(www)
Violation/Comment:

5. Safety Instruction to Personnel 256(ll) & 256(uu)

☐ N/A

Instruction for personnel caring for patients who cannot be released in accordance with 256(cc):
☐ Yes ☐ No Initial and annual radiation safety instruction provided to personnel?
☐ Yes ☐ No Records of individuals that received safety instructions were available?
☐ Yes ☐ No Reviewed records include all required information?
Violation/Comment:

6. Safety Precautions for Patients 256(mm) & 256(vv)

☐ N/A

For patients who cannot be released in accordance with 256(cc):
☐ Yes ☐ No Private room provided, room properly posted, & visit duration noted?
☐ Yes ☐ No Proper waste handling, surveys, emergency response equipment available?
☐ Yes ☐ No ☐ N/A RSO notified immediately if patient dies?
Violation/Comment:

7. Release of Individuals 256(cc) 256(bb)

☐N/A

☐ Yes ☐ No Individuals released only when the TEDE to others is not likely exceed 0.5 rem?
☐ Yes ☐ No ☐ N/A Individuals with temporary eye plaques released only when exposure to others is less than 5 mR/hr at 1 meter?
☐ Yes ☐ No Records of the release of patients are maintained for 3 years? 256(cc)(3)
☐ Yes ☐ No Reviewed records include the required information? 256(cc)(3)(A) & (B)
☐ Yes ☐ No Written instructions were provided when the TEDE to others is likely to exceed 0.1 rem? 256(cc)(2)
☐ Yes ☐ No Reviewed written instructions contain the required information? 256(cc)(2)
☐ Yes ☐ No Surveys performed of confinement area after patient is release? 256(bb)
☐ Yes ☐ No Reviewed records of surveys maintained and complete? 256(bb)
Violation/Comment:

8. Source Accountability Sealed Sources

☐N/A

☐ N/A **Implants:**
☐ Yes ☐ No Surveys performed after implant and after removal? 256(ss)(2)
☐ Yes ☐ No Reviewed records of surveys complete and maintained for 3 years? 256(ss)(3)

☐ N/A **Brachytherapy Source Inventory:**
☐ Yes ☐ No Brachytherapy source use & storage was documented? 256(tt)(3)
☐ Yes ☐ No Reviewed records of use & storage of brachytherapy sources were complete?
Violation/Comment:

Medical Therapy Inspection Inspection Date:

Licensee: License No.: L -

Sealed & Unsealed Therapy Program Information

9. Brachytherapy Source Calibration Measurements ☐ N/A	☐ Yes ☐ No Calibration measurements performed for brachytherapy sealed sources prior to the first medical use occurring on or after October 1, 2000. 256(ww)(1)-(3) ☐ Yes ☐ No Reviewed records include all required information. 256(ww)(4) ☐ Yes ☐ No Records maintained for 3 years. 256(www) Violation/Comment:
10. Eye Applicator Activity Calculation ☐ N/A	☐ Yes ☐ No Eye applicator source activity calculated by authorized medical physicist to determine treatment time. 256(xx)(1) ☐ Yes ☐ No Reviewed records include all required information. 256(xx)(2) ☐ Yes ☐ No Records maintained for 3 years. 256(www) Violation/Comment:
11. Protective Equipment and Emergency Procedures	☐ N/A **Unsealed Therapy:** ☐ Yes ☐ No Radiopharmaceutical syringes and vials properly labeled? 256(aa) ☐ Yes ☐ No Decontamination equipment & supplies available? ☐ Yes ☐ No Procedures for decontamination available? ☐ Yes ☐ No Procedures were followed for contamination events? ☐ Yes ☐ No Reviewed records include all required information? ☐ N/A **Sealed Source Therapy:** ☐ Yes ☐ No Source retrieval supplies were available? ☐ Yes ☐ No Source retrieval procedures were available? ☐ Yes ☐ No ☐ N/A Source retrieval procedures were followed? ☐ Yes ☐ No ☐ N/A Reviewed records include all required information? Violation/Comment:
12. Use Locations	☐ Yes ☐ No RAM only used at authorized locations? ☐ Yes ☐ No Use of RAM at remote use locations? ☐ Yes ☐ No ☐ N/A Release surveys performed after RAM use at remote locations? Violation/Comment:
13. Performance Based	
Comments/Violation:	

Medical Therapy Inspection	Inspection Date:
Licensee:	License No.: L -
Inspector Facility Survey	
Instruments/Probes used: **Manuf, model, S/N, calib. date...**	

-Insert drawings & additional pages (scanned documents, photos, etc…) here.

Texas Department of State Health Services
Inspection Unit – Radioactive Material Group
Compliance Activity Data Form

Permit Data:

Permit Type and Number: **L**
Site Number:
URGENT - ROUTE TO:
Activity City:
Prime Use Code:
Name:

Activity Data:

Activity Code:
Inspection Use Code:
Inspector Name: **DBAILEY001**
Type Inspection:
Activity Date:

Preparatory	Travel	Waiting	Activity	Report	Total	Cost
0.0	0.0	0.0	0.0	0.0	0.0	$ 0.00

Inspector Comments:

Low Level Waste*: Record Volume in cubic feet (ft^3), [55 gallon drum = 7.35 ft^3].
Volume Generated/Year
Principle isotopes, form, and approximate activities of each
Volume in Storage
Principle isotopes, form, and approximate activities of each
* Do not record waste that can be held for decay and disposed of in a landfill.

Review Data:

Inspection Status Press F4:
Next Due Date (required if "Special" inspection status is selected):

	Code	Count	S L	Code	Count	S L	Code	Count	S L	Code	Count	S L
1st												
5th												
9th												

QA Reviewer Comments:

QA Reviewer:
Date Reviewed:
Data Entry:
Date Entered:

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

April 13, 2010

The Honorable Edward J. Markey, Chairman
Congress of the United States
House of Representatives
Subcommittee on Energy and Environment
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: Information request for oversight of the treatment of patients with radioisotopes.

Dear Chairman Markey:

The Texas Commission on Environmental Quality (TCEQ) has received your letter dated March 18, 2010. The regulatory oversight of radioactive materials is administered by two state agencies: the Texas Department of State Health Services (TDSHS), and the Texas Commission on Environmental Quality (TCEQ). The TCEQ does not have regulatory oversight for the treatment of patients with radioisotopes. This regulatory oversight is administered in Texas by TDSHS. The TCEQ Radioactive Materials Program does administers radioactive material licenses and authorizations for in situ uranium recovery; radioactive waste processing, storage and disposal; low-level radioactive waste disposal; by-product material disposal; and disposal of naturally-occurring radioactive materials (NORM) that are not related to oil and gas production.

We have confirmed receipt of a copy of this correspondence with Mr. Richard Ratliff, Radiation Safety Licensing Branch Manager, at TDSHS. It is our understanding that Mr. Ratliff will address your concerns on behalf of the State of Texas and respond within the requested time frame. If TCEQ can be of further assistance, please contact me at (512) 239-6731 or by electronic mail at sjablons@tceq.state.tx.us.

Sincerely,

Susan Jablonski P.E., Director
Radioactive Materials Division